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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,402	08/06/2003	Edward S. Ahn	220318	1210
23460 7590 07/27/2007 LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731			EXAMINER SOROUSH, ALI	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 07/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/635,402	Applicant(s) AHN, EDWARD S.	
	Examiner Ali Soroush	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 18-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 69-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 03/27/2006 in response to the Office Action mailed on 12/26/2006 is acknowledged.

Status of the Claims

Claims 18-68 have been withdrawn, claim 1 has been amended, and claims 69-73 have been newly added. Therefore, claims 1-17 and 69-73 remain pending examination for patentability.

Election/Restrictions

Office Action mailed on 10/04/2006 set forth a restriction requirement. In response filed on 11/06/2006 applicant elected Group I (claims 1-17) with traverse. In Office Action mailed on 12/26/2006 the examiner acknowledged the election but failed to respond applicant's argument. Applicant has requested that the examiner address applicant's arguments set forth in the response filed on 11/06/2006.

Applicant argues that the inventions of Group II and Group III are in fact related to the invention of Group I and that a search of all claims would not impose an undue burden on the examiner. The examiner has fully considered the applicants argument and has found them not to be persuasive. The three distinct products of Groups I, II, III are only related by the fact that each comprises tricalcium phosphate. However, the formation of tricalcium phosphate of a specific particle size is dependent upon the method of production. Where in Group I the TCP must have a very small particle size and thereby limit methods that can be used to produce the TCP and the ensuing crystal

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characteristics. However, the inventions of Group II and III require crystal structure characteristics that are different from that of Group I and there require different method of production. For the foregoing reasons the search of the different groups would be an undue burden on the examiner as further discussed in the Office action mailed on 12/26/2006. Therefore, the restriction requirement is made final.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-7 and 12-17 were rejected under 35 U.S.C. 102(e) as being anticipated by (US Patent 6840961, Published 01/11/2005, Filed 12/21/2001).

Applicant argues that Tofighi et al. does not anticipate the instant composition because Tofighi et al. teaches a “calcium phosphate precursor” having a mixture of two different calcium phosphate materials that are capable of forming a poorly-crystalline hydroxyapatite implant. Applicant further argues that Tofighi et al. teaches against the formation of TCP articles, stating that they are undesirable because they degrade rapidly in vivo but lack sufficient strength for weight bearing applications. The examiner has considered applicants arguments and has found them to be persuasive. Therefore the rejection of claims 1-3, 5-7, and 12-17 under 35 U.S.C. 102(e) **is withdrawn**.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Dalal et al. (US Patent 6949251, Published 09/27/2005, Filed 09/21/2001) in view of Ying et al. (US Patent 6013591, Published 01/11/2000) .

Applicant argues that Dalal et al. in view of Ying et al. does not make obvious the instant claims. Applicant argues that one would not be motivated to combine the teachings of Dalal et al. with Ying et al. because Dalal et al. is directed to tricalcium phosphate implant and Ying et al. is directed to an apatite implant. Therefore, one would not arrive at a composition of TCP having the instant particle size, crystal size, and surface area as the instant by combining Ying et al. because TCP and hydroxyapatite has different physical and chemical properties which require different synthetic and calcinations procedures to produce. Applicant's arguments have been fully considered

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by the examiner and found to be persuasive. Therefore, the rejection of claims 1-17 under 35 U.S.C. 103(a) is **withdrawn**.

New Grounds of Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2, 3, 5, 6, 12, 13, 14 and 69-73 rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al. (US Patent Application, Published 08/27/2002).

Tanaka et al. teaches a biomaterial for induction of osteoanagenesis comprising a copolymer of lactic acid, glycolic acid, and capralactone and tricalcium phosphate. The ratio of the TCP to polymer is 1:0.1 to 1:2. The TCP particle size to be used should be in the range of 0.1 to 200 μm and can be sintered at 650 to 1500°C to provide for a denser particle. (See column 16, claims 1,2; column 18, claims 12-14; column 8, Lines 1 and 40-43). In regards to the surface area and crystal size, it is the examiner position that these characteristics would necessarily be present in the TCP used in the Tanaka et al. composition. One would expect because the TCP used in Tanaka et al. has a similar particle size and is made by the same process of being sintered at a similar temperature as the instantly claimed sintering temperature. In regards to the newly added limitation of the compressive strength and densification it is note by the examiner that the limitation reads “can be” which is a optional claim language and is not given patentable weight. For the foregoing reasons the instant invention is anticipated.

2 . Claims 15-17 are rejected as being unpatentable over Tanaka et al. (US Patent Application, Published 08/27/2002) in view of Dalal et al. (US Patent 6949251, Published 09/27/2005, Filed 09/21/2001).

Applicant Claims

Applicant claims a composition comprising particulate tricalcium phosphate (TCP) having an average particle size of about 5 μm or less, an average crystal size of about 250 nm or less and a surface area of about 20 m^2/g or greater. The composition can further include a secondary additive such as a biological additive.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tanka et al. are presented above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Tanaka et al. does not teach a composition comprising a biological additive. This deficiency is cured by the teachings of Dalal et al.

Dalal et al. teaches, "**A composition comprising porous β -tricalcium phosphate (β -TCP) granules that have a particle size of 0.1 –2 mm and that comprise a multiplicity of pores ...**" (See column 59, claim 1). "**The composition of any one of claims 1 to 5, further comprising a bioactive agent.**" (See column 59, claim 13). "**The composition of claim 13, wherein the bioactive agent is a bone morphogenic protein.**" (See column 59, claim 14). "**The composition of claim 13, wherein the**

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bioactive agent is an osteogenic protein ..." (See column 59, claim 16). "The invention also provides an implantable prosthetic device ..." (See abstract).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Tanaka et al. and Dalal et al. One would have been motivated to do so combine the teachings of Tanaka et al. and Dalal et al. so as to provide for a more efficient implant that induces osteoanagesis. Both the Tanka et al. implant and the Dalal et al. give induce osteoagenesis and there the combination of the two would have been obvious because it would have provided an additive osteoagenesis effect. For the foregoing reasons the instant compositions would have been obvious to one of ordinary skill in the art at the time of the instant invention.

4. Claims 8-11 are rejected as being unpatentable over Tanaka et al. (US Patent Application, Published 08/27/2002) in view of Kijima et al. (US Patent 5185177, Published 02/09/1993).

Applicant Claims

Applicant claims a composition comprising particulate tricalcium phosphate (TCP) having an average particle size of about 5 μm or less, an average crystal size of about 250 nm or less and a surface area of about 20 m^2/g or greater. The composition can further include a secondary additive such as a structural additive.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tanka et al. are presented above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Tanaka et al. does not teach a composition comprising a structural additive. This deficiency is cured by the teachings of Kijima et al.

Kijima et al. teaches a ceramic implant comprising α -tricalcium phosphate and zirconia. "The present inventors have conducted extensive researches in view of the above problems. As a result, they have found that a ceramic implant having a coating layer of a porous sintered body of a mixture of α -TCP and zirconia, or hydroxy apatite and zirconia, on the surface of a sintered body of zirconia, has high mechanical strength and is free from breakage in a living body, and the biologically active surface porous layer bonded firmly to the core material, is capable of bonding to vital tissue in the living body, whereby it can be a material durable for use for a long period of time." (See column 1, Lines 49-59).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Tanaka et al. with Kijima et al. One would have been motivated to combine the implants of Tanaka et al. and Kijima et al. so as to provide an implant that has both osteoagenic properties as well as increased mechanical strength. Therefore, a TCP implant composition having high mechanical strength and osteoagenic would have been obvious to one of ordinary skill in the art. For the foregoing reasons the instant composition would have been obvious to one of ordinary skill in the art at the time of the instant invention.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
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